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Support for new claim 21 can be found inter alia in the specification, as originally filed, on page 7, line 11.

Support for new claim 22 can be found inter alia in the specification, as originally filed, on page 7, line 36.

Support for new claim 23 can be found *inter alia* in the specification, as originally filed, on page 1, lines 14-18.

Support for new claim 24 can be found *inter alia* in the specification, as originally filed, on page 1, lines 31-37.

Support for new claim 25 can be found inter alia in the specification, as originally filed, on page 2, lines 31-34.

## INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following documents which are listed on Form PTO-1449 (Exhibit A) and are also listed below.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action on the merits. Thus, this Information Disclosure Statement should be entered and considered.

This application is a continuation of U.S. Serial No. 09/355,543, filed July 29, 1999, now allowed.

Copies of the documents listed below as items 1-25, 33-46, 49-62, 66-84, 86-91, 93, 96, 102, and 104 have previously been submitted

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to the U.S. Patent Office and items 19 and 96 have previously been cited by the U.S. Patent and Trademark Office in connection with U.S. Serial No. 09/355,543 upon which the subject application relies for an earlier filing date pursuant to 35 U.S.C. § 120. Therefore, in accordance with 37 C.F.R. §1.98(d), copies of the previously submitted documents are not provided. Item 26 below is a citation to U.S. Serial No. 09/355,543, now allowed, a copy of which is attached hereto as **Exhibit 1**, of which the current application is a continuation. A copy of the documents listed as items 27-32, 47-48, 63-65, 85, 92, 94-95, 103, and 105 are attached hereto as **Exhibits 2-18**, respectively.

- 1. U.S. Patent No. 4,139,561 (Onopchenko et al.) issued February 13, 1979;
- 2. U.S. Patent No. 4,216,341 (Onopchenko et al.) issued August 5, 1980;
- U.S. Patent No. 4,219,679 (Onopchencko et al.) issued
   August 26, 1990;
- 4. U.S. Patent No. 4,255,313 (Antonoplos et al.) issued March 10, 1981;
- 5. U.S. Patent No. 4,305,751 (Sabourin et al.) issued December 15, 1981;
- 6. U.S. Patent No. 4,322,420 (Kobayashi et al.) issued March 30, 1982;
- 7. U.S. Patent No. 4,943,533 (Mendelsohn et al.) issued July

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24, 1990;

- 8. U.S. Patent No. 5,089,499 (Barker et al.) issued February 18, 1992;
- 9. U.S. Patent No. 5,256,781 (Primeau et al.) issued October 26, 1993;
- U.S. Patent No. 5,457,105 (Barker) issued October 10, 10. 1995;
- U.S. Patent No. 5,475,001 (Barker) issued December 12, 1995; 11.
- 12. U.S. Patent No. 5,580,870 (Barker) issued December 3, 1996;
- 13. U.S. Patent No. 5,616,582 (Barker) issued April 1, 1997;
- 14. U.S. Patent No. 5,639,881 (Skibo et al.) issued June 17, 1997;
- 15. U.S. Patent No. 5,654,307 (Bridges et al.) issued August 5, 1997;
- U.S. Patent No. 5,686,458 (Lee et al.) issued November 11, 16. 1997;
- 17. U.S. Patent No. 5,707,992 (Webber et al. ) issued January 13, 1998;
- 18. U.S. Patent No. 5,710,145 (Engel et al.) issued January 20, 1998;

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- 19. U.S. Patent No. 5,747,498 (Schnur et al.) issued May 5, 1998;
- 20. U.S. Patent No. 5,770,195 (Hudziak et al.) issued January 23, 1998;
- 21. U.S. Patent No. 5, 817,674 (Clemence et al.) issued October 6, 1998;
- 22. U.S. Patent No. 5,821,246 (Brown et al.) issued October 13, 1998;
- 23. U.S. Patent No. 5,948,784 (Fujiwara et al.) issued September 7, 1989;
- 24. U.S. Patent No. 6,004,979 (Clemence et al.) issued December 21, 1999;
- 25. U.S. Patent No. 6,130,218 (Morsdorf et al.) issued October 10, 2000;
- 26. U.S. Serial No. 09/355,534, filed on July 29, 1999 (Allen
  et al.)(Exhibit 1);
- 27. U.S. Patent No. 6,476,040, issued November 5, 2002, Norris et al. (Exhibit 2);
- 28. U.S. Patent No. 6,169,091, issued January 2, 2001, Cockerill et al. (Exhibit 3);

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- 30. U.S. Patent No. 5,214,144, issued May 25, 1993, Tai et al.
  (Exhibit 5);
- 31. U.S. Patent No. 4,281,127, issued July 28, 1981, LeMahieu et al. (Exhibit 6);
- 32. U.S. Patent No. 3,800,039, issued March 26, 1974, Marquis et al. (Exhibit 7);
- 33. Australian Patent No. AU 18422/92 filed June 22, 1992;
- 34. Australian Patent No. AU 31010/93 filed January 4, 1993;
- 35. Australian Patent No. AU 38130/95 filed November 8, 1995;
- 36. Canadian Patent No. CA 2,086,968 filed November 12, 1992;
- 37. German Patent No. DE 2,936,705 filed September 11, 1979;
- 38. European Patent No. EP 0 498 723 filed February 5, 1992;
- 39. European Patent Application Publication No. EP 0 520 722 Al, published December 30, 1992;
- 40. European Patent No. EP 0 566 226 Bl filed January 15, 1993;
- 41. European Patent Application Publication No. EP 0 579 496 Al, published January 19,1994;

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November 17, 2003 Preliminary Amendment

- 42. European Patent Application Publication No. EP 0 602 851 Al, published June 22, 1994;
- 43. European Patent Application Publication No. EP 0 635 498 Al, published January 25, 1995;
- 44. European Patent Application Publication No. EP 0 635 507 Al, published January 25, 1995;
- 45. European Patent Application Publication No. EP 0 667 165 Al, published August 16, 1995;
- 46. European Patent Application Publication No. EP 0 787 722 Al, published August 6, 1997;
- 47. European Patent Application Publication No. EP 0 837 063 A1, published April 22, 1998 (Exhibit 8);
- 48. European Patent Application Publication No. EP 1 044 969
  A2, published October 18, 2000 (Exhibit 9);
- 49. Japanese Patent No. JP 1048048 filed August 19, 1987;
- 50. Japanese Patent No. JP 5208911 filed June 22, 1992;
- 51. Japanese Patent No. JP 6192235 filed July 15, 1993;
- 52. Japanese Patent No. JP 6205969 filed July 3, 1985;
- 53. Japanese Patent No. JP 6336481 filed December 3, 1993;
- 54. Japanese Patent No. JP 7101941 filed September 30, 1993;

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- 55. Japanese Patent No. JP 7118266 filed January 28, 1994;
- 56. Japanese Patent No. JP 7126255 filed September 7, 1994;
- 57. Japanese Patent No. JP 7188244 filed October 1, 1994;
- 58. Japanese Patent No. JP 7309873 filed November 9, 1992;
- 59. Japanese Patent No. JP 8099962 filed July 15, 1993;
- 60. Japanese Patent No. JP 8151377 filed November 25, 1994;
- 61. Japanese Patent No. JP 9165385 filed August 25, 1995;
- 62. Japanese Patent No. JP 9221478 filed February 4, 1997;
- 63. Japanese Patent No. 673025, published March 15, 1994 (Exhibit 10 application with English abstract);
- 64. Japanese Patent No. 10036325, published February 10, 1998

  (Exhibit 11 application with English abstract);
- 65. Japanese Patent No. 10036326, published February 10, 1998 (Exhibit 12 application with English abstract);
- 66. New Zealand Patent No. NZ 0245662 filed January 15, 1993;
- 67. Russian Patent No. RU 2127263 filed January 15, 1993;
- 68. PCT International Application Publication No. WO 92/20642, published November 26, 1992;

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- 69. PCT International Application Publication No. WO 95/03283 published February 2, 1995;
- 70. PCT International Application Publication No. WO 95/15758 published June 15, 1995;
- 71. PCT International Application Publication No. WO 96/09294 published March 28, 1996;
- 72. PCT International Application Publication No. WO 96/15118 published May 23, 1996;
- 73. PCT "International Application Publication No. WO 96/28430, published September 19, 1996;
- 74. PCT International Application Publication No. WO 96/30347 published October 3, 1996;
- 75. PCT International Application Publication No. WO 96/40210, published December 19, 1996;
- 76. PCT International Application Publication No. WO 97/03069, published January 30, 1997;
- 77. PCT International Application Publication No. WO 97/30035, published August 21, 1997;
- 78. PCT International Application Publication No. WO 97/32856, published September 12, 1997;
- 79. PCT International Application Publication No. WO 97/41896, published November 13, 1997;

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- 80. PCT International Application Publication No. WO 98/13354 published April 2, 1998;
- 81. PCT International Application Publication No. WO 99/03803 published January 28, 1999;
- 82. PCT International Application Publication No. WO 99/55683 published November 4, 1999;
- 83. PCT International Application Publication No. WO 99/60023 published November 25, 1999;
- 84. PCT International Application Publication No. WO 00/31048 published February 6, 2000;
- 85. PCT International Application Publication No. WO 01/034574, published May 17, 2001 (Exhibit 13);
- 86. Agharkar, S., et al., "Enhancement of Solubility of Drug Salts by Hydrophilic Counterions: Properties of Organic Salts of an Antimalarial Drug," Journal of Pharmaceutical Sciences 1976, Vol. 65, No. 5, p.p. 747-749;
- 87. Berge, S., et al., "Pharmaceutical Salts," Journal of Pharmaceutical Sciences 1977, Vol. 66, No. 1, p.p. 1-19;
- 88. Bleicher, L., et al., "Aryl- and Hetero-Alkyne Coupling Reactions Catalyzed by Palladium on Carbon and Cul in an Aqueous Medium," Synlett 1995, November, p.p. 1115-1116;
- 89. Bleicher, L., et al., "A Practical and Efficient Synthesis of the Selective Neuronal Acetylcholine-Gated Ion

Applicants Douglas J. M. Allen, et al. Not Yet Known Serial No. November 17, 2003 Preliminary Amendment

Page 17

Agonist (S) - (-) -5-Ethynyl-3- (1-methyl-2pyrrolidinyDpyridine Maleate (SIB-1508Y), " Journal of Organic Chemistry 1998, Vol. 63, No. 4, p.p. 1109-1118;

- 90. Botros, S., et al., "Synthesis of Certain Nitro-quinazoline Derivatives Structurally Related to Some Chemotherapeutic Agents, " Egypt. J. Pharm. Sci. 1972, Vol. 13, No. 1, p.p. 11-21;
- 91. Cerny, A., "Solvolysis of Some 1-(8a-ergolyinyl)-3,3-Diethylureas and Their Salts," Collection Czechoslovak Chem. Commun. 1987, Vol. 52, p.p. 1331-1339;
- 92. Draetta, G. et al., "Cell Cycle and Cancers," Annual Rep. Med. Chem. 1996, pp. 241-246 (Exhibit 14);
- 93. Hussain, M., et al., "Parenteral Formulation of the Kappa Agonist Analgesic, DuP 747, via Micellar Solubilization," Pharmaceutical Research 1992, Vol. 9, No. 6, p.p. 750-752;
- 94. Melissaris, A.P. et al., "A Simple and Economical Synthetic Route to p-Ethynylaniline and Ethynyl-Terminated Substrates" (1994) J. Org. Chem. 59: 5818-5821 (Exhibit 15);
- 95. et al., "A Convergent Montalbetti, C. Synthesis of Functionalized B-seco Taxane Skeletons" (1995) Tetrahedron Letters 36(33): 5891-5894 (Exhibit 16);
- 96. Moyer, J., et al., "Induction of Apoptosis and Cell Cycle Arrest by CP-358,774, an Inhibitor of Epidermal Growth Factor Receptor Tyrosine Kinase, " Cancer Research 1997, Vol. 57, p.p. 4838-4848;

Applicants : Douglas J. M. Allen, et al. Serial No. : Not Yet Known November 17, 2003 Preliminary Amendment Page 18

- 97. Norris, T., et al., "Discovery of a New Stable Polymorph of 4- (3-ethynylphenylamino) 6,7-bis (2-methoxy-ethoxy) quinazolinium Methanesulfonate Using Near-Infrared Spectroscopy to Monitor Form Change Kinetics," J. Chem. Soc., Perkin Trans. 2000, Vol. 2, p.p. 1233-1236;
- 98. Onopchenko, et al., "Selective Catalytic Hydrogenation of Aromatic Nitro Groups in the Presence of Acetylenes. Synthesis of (3-Aminophenyl)acetylene via Hydrogenation of Dimethylcarbinol Substituted (3-Nitrophenyl)acetylene over Heterogeneous Metallic Ruthenium Catallyst," Journal of Organic Chemistry 1979, Vol. 44, No. 8, p.p. 1233-1236;
- 99. Pollack, V., et al., "Inhibition of Epidermal Growth Factor Receptor-Associated Tyrosine Phosphorylation in Human Carcinomas with CP-358,774: Dynamics of Receptor Inhibition In Situ and Antitumor Effects in Athymic Mice," Journal of Pharmacology and Experimental Therapeutics, 1999, Vol. 291, No. 2, p.p. 739-748;
- 100. Rosenberg, S., et al., "Studies Directed toward the Design of Orally Active Renin I-nhibitors. 2. Development of the Efficacious, Bioavailable Renin Inhibitor (2S)-2-Benzyl-3-[[(1-methylpiperazin-4-yl)sulfonyl]propionyl]-3-thiazol-4-yl-L-alanine Amide of (2S, 3R, 4S)-2-Amino-1-cyclohexyl-3, 4-dihydroxy-6-methylheptane (A-72517), " J. Med. Chem. 1993, Vol. 36, p.p. 460-467;
- 101. Smaill, J., et al., "Tyrosine Kinase Inhibitors. 17.

  Irreversible Inhibitors of the Epidermal Growth Factor

  Receptor: 4-(Phenylamino)quinazoline- and 4
  (Phenylamino)pyrido[3, 2-d]pyrimidine-6-acrylamides Bearing

Serial No. : Not Yet Known

November 17, 2003 Preliminary Amendment

Page 19

Additional Solubilizing Functions, " J. Med. Chem. 2000, Vol. 43, p.p. 1380-1397;

- 102. Spurlock, C., "Increasing Solubility of Enoxacin and Norfloxacin by Means Salt Formation," Journal of Parenteral Science and Technology 1986, Vol. 40, No. 2, p.p. 70-72;
- 103. Sun Cunji et al., (1981) Yaoxue Xuebao 16(8): 564-570 C.A. 96 122727 (Exhibit 17 abstract only).
- 104. Takalo, H., et al., "Synthesis of Some Substituted Dimethyl and Diethyl 4-(Phenylethynyl)-2,6-pyridine-dicarboxylates,"
  Acta Chemica Scandinavica, Vol. B42, p.p. 448-454; and
- 105. Trillo et al., (1993) <u>Tratado de Farmacia Galencia,</u>

  <u>Primeria Edicion</u>, pp. 81, 83, 84 (Exhibit 18 document and translation).

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee, other than the enclosed \$770.00 application filing fee, is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

John P. White

Registration No. 28,678

Gary J. Gershik

Registration No. 39,992 Attorneys for Applicants

Cooper & Dunham LLP

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(212) 278-0400

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26	US	09	3	5	5	5	3	4	7/29/99	Allen et al. (Exhibit 1)					
27	US	6	4	7	6	0	4	0	11/5/02	Norris et al. (Exhibit 2)					
28	US	6	1	6	9	0	9	1	1/2/2001	Cockerill et al. (Exhibit 3)					
29	US	6	0	0	4	9	6	7	12/21/99	McMahon et al. (Exhibit 4)					
30	US	5	2	1	4	1	4	4	5/25/93	Tai et al. (Exhibit 5)					
31	us	4	2	8	1	1	2	7	7/28/81	LeMahieu at al. (Exhibit 6)					
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64	JР	10	0	3	6	3	2	5	2/10/98	JP (Exhibit 11)				
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93										nulation of the Kappa Agon earch 1992, Vol. 9, No. 6, p.p.			747, via M	licellar
94	Melissaris, A.P. et al., "A Simple and Economical Synthetic Route to p-Ethynylaniline and Ethynyl-Terminated Substrates" (1994) J. Org. Chem. 59: 5818-5821. (Exhibit 15)													
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## Atty. Docket No. Serial No. **Form PTO-1449 U.S. Department of Commerce** 62815-A-PCT-US/ Not Yet Known Patent and Trademark Office JPW/GJG/ACK **Applicants** INFORMATION DISCLOSURE CITATION Douglas J.M. Allen et al. (Use several sheets if necessary) **Filing Date** Group Herewith 1624 U.S. PATENT DOCUMENTS Ex a miner Filing Date **Document Number** Name Class Subclass Initial / if Appropriate Item No. 21 US 5 8 10/6/98 Clemence et al. US 5 | 8 2 1 2 4 10/13/98 Brown et al. 6 22 5 9 US 4 8 7 8 4 09/07/99 Fujiwara et al. 23 US 6 0 0 4 9 7 12/21/99 Clemence et al. 24 US 6 3 0 2 8 10/10/00 Morsdorf et al. 25 FOREIGN PATENT DOCUMENTS **Document Number** Date Country Class Subclass Translation Yes No 76 WO 0 3 0 6 9 01/30/97 PCT 08/21/97 PCT WO 9 7 3 0 0 3 5 77 wo 2 09/12/97 PCT 9 7 3 8 5 6 78 9 WO 9 7. 8 11/13/97 PCT 4 1 6 80 WO 9 8 3 5 04/02/98 PCT 3 4 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Rosenberg, S., et al., "Studies Directed toward the Design of Orally Active Renin Inhibitors. 2. Development of the Efficacious, Bioavailable Renin Inhibitor (2S)-2-Benzyl-3-[[(l-methylpiperazin-4-100 yl)sulfonyl] propionyl]-3-thiazol-4-yl-L-alanine Amide of (2S, 3R, 4S)-2-Amino-l-cyclohexyl-3, 4dihydroxy-6- methylheptane (A-72517)," J. Med. Chem. 1993, Vol. 36, p.p. 460-467. Smaill, J., et al., "Tyrosine Kinase Inhibitors. 17. Irreversible Inhibitors of the Epidermal Growth Factor 101 Receptor: 4-(Phenylamino)quinazoline- and 4-(Phenylamino)pyrido[3,2-d]pynmidine-6-acrylarnides Bearing Additional Solubilizing Functions," J. Med. Chem. 2000, Vol. 43, p.p. 1380-1397. Spurlock, C., .. "Increasing. Solubility of Enoxacin and Norfloxacin by Means Salt Formation," Journal of 102 Parenteral Science and Technology 1986, Vol. 40, No. 2, p.p. 70-72. 103 Sun Cunji et al., (1981) Yaoxue Xuebao 16(8): 564-570 C.A. 96 122727 (Exhibit 17 – abstract only).

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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EXAMINER

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Applicants: Douglas J. M. Allen et al. Serial No.: Not Yet Known Filed : Herewith

Exhibit A

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